PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

AWAPATENT AB
Box 5117
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Date of mailing (day/month/year)
31 January 2001 (31.01.01)

Applicant's or agent's file reference
2004309

IMPORTANT NOTIFICATION

International application No.
PCT/SE00/01369

International filing date (day/month/year)
28 June 2000 (28.06.00)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address
SOLEM, Jan, Otto
Nordmannavägen 20
S-237 31 Bjärred
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [X] the nationality [X] the residence

Name and Address
SOLEM, Jan, Otto
Wallenrutistrasse 14
CH-8234 Stetten
Switzerland

State of Nationality: NO
State of Residence: CH
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[X] the designated Offices concerned
[ ] the elected Offices concerned
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The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
F. Baechler

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
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Office, PCT
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CP2/5C24
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in its capacity as elected Office

Date of mailing (day/month/year) 15 February 2001 (15.02.01)	
International application No. PCT/SE00/01369	**Applicant's or agent's file reference** 2004309
International filing date (day/month/year) 28 June 2000 (28.06.00)	**Priority date** (day/month/year) 29 June 1999 (29.06.99)
Applicant SOLEM, Jan, Otto et al	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   17 January 2001 (17.01.01)

   [ ] in a notice effecting later election filed with the International Bureau on:

   _____

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Claudio Borton
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

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(71) Applicants and
(72) Inventors: **SOLEM, Jan, Otto** [SE/SE]; Nordmannavägen 20, S-237 31 Bjärred (SE). **KIMBLAD, Per, Ola** [SE/SE]; Saturnusgatan 9, S-224 57 Lund (SE).

(74) Agent: **AWAPATENT AB**; Box 5117, S-200 71 Malmö (SE).

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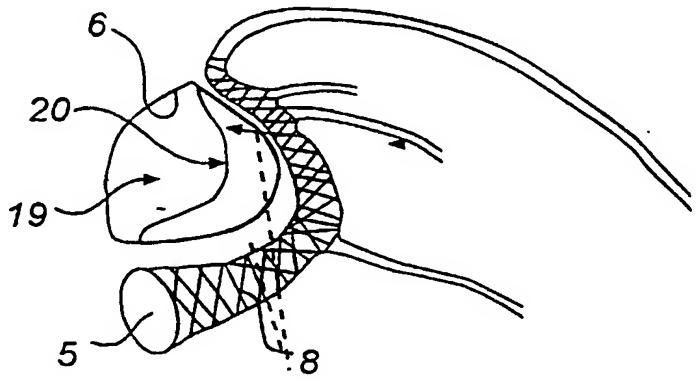
(54) Title: DEVICE AND METHOD FOR TREATMENT OF MITRAL INSUFFICIENCY



(57) Abstract: A device for treatment of mitral annulus dilatation comprises an elongate body (8) having two states. In a first of these states the elongate body (8) is insertable into the coronary sinus (5) and has a shape adapting to the shape of the coronary sinus (5). When positioned in the coronary sinus (5), the elongate body (8) is transferable to the second state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus (5) and the radius of curvature as well as the circumference of the mitral annulus (6) is reduced.

WO 01/00111 A1

DEVICE AND METHOD FOR TREATMENT OF MITRAL INSUFFICIENCY

The present invention generally relates to a device and a method for treatment of mitral insufficiency and, more specifically, for treatment of dilatation of the mitral annulus.

Mitral insufficiency can result from several causes, such as ischemic disease, degenerative disease of the mitral apparatus, rheumatic fever, endocarditis, congenital heart disease and cardiomyopathy. The four major structural components of the mitral valve are the annulus, the two leaflets, the chordae and the papillary muscles. Any one or all of these in different combinations may be injured and create insufficiency. Annular dilatation is a major component in the pathology of mitral insufficiency regardless of cause. Moreover, many patients have a mitral insufficiency primarily or only due to posterior annular dilatation, since the annulus of the anterior leaflet does not dilatate because it is anchored to the fibrous skeleton of the base of the heart.

Studies of the natural history of mitral insufficiency have found that totally asymptomatic patients with severe mitral insufficiency usually progress to severe disability within five years. At present the treatment consists of either mitral valve replacements or repair, both methods requiring open heart surgery. Replacement can be performed with either mechanical or biological valves.

The mechanical valve carries the risk of thromboembolism and requires anticoagulation, with all its potential hazards, whereas biological prostheses suffer from limited durability. Another hazard with replacement is the risk of endocarditis. These risks and other valve related complications are greatly diminished with valve repair.

Mitral valve repair is theoretically possible if an essentially normal anterior leaflet is present. The basic four techniques of repair include the use of an annuloplasty ring, quadrangular segmental resection of diseased posterior leaflet, shortening of elongated chordae, and transposition of posterior leaflet chordae to the anterior leaflet.

Annuloplasty rings are needed to achieve a durable reduction of the annular dilatation. All the common rings are sutured along the posterior mitral leaflet adjacent to the mitral annulus in the left atrium. The Duran ring encircles the valve completely, whereas the others are open towards the anterior leaflet. The ring can either be rigid, like the original Carpentier ring, or flexible but non-elastic, like the Duran ring or the Cosgrove-Edwards ring.

Effective treatment of mitral insufficiency currently requires open-heart surgery, by the use of total cardiopulmonary by-pass, aortic cross-clamping and cardioplegic arrest.

To certain groups of patient, this is particular hazardous. Elderly patients, patients with a poor left ventricular function, renal disease, severe calcification of the aorta, previous cardiac surgery or other concomitant diseases, would in particular most likely benefit from a less invasive approach, even if repair is not complete. The current trend towards less invasive coronary artery surgery, without cardiopulmonary by-pass, as well as PTCA will also call for a development of a less invasive method for repair of the often concomitant mitral insufficiency.

Therefore, a first object of the present invention is to provide a device and a method for treatment of mitral insufficiency without the need for cardiopulmonary by-pass and opening of the chest and heart.

A second object of the invention is to provide reduction of the mitral annulus using less invasive surgery.

These and other objects are attained by a device as defined in the appended claim 1, and by a method as defined in the appended claim 7.

According to the present invention, a device for treatment of mitralis insufficiency comprises an elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first state of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second state of which the elongate body is transferable from the said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus.

Preferably, means are provided for the transfer of the elongate body to the second state by bending and/or shortening it from a larger radius of curvature to a smaller radius of curvature.

The transfer means may comprise means for bending and/or shortening the elongate body by a preferably asymmetric contraction thereof.

Further, the elongate body may comprise a memory material providing the transfer to the second state.

In a preferred embodiment, the elongate body may comprise a stent. In an alternative embodiment, the device according to the invention may comprise several stent sections and said bending and/or shortening means may comprise wires for shortening the distance between the stent sections.

According to a second aspect, a method of reducing the circumference of the mitral valve annulus comprises the steps of inserting an elongate body into the coronary sinus in the vicinity of the posterior leaflet of the

mitral valve, and then providing a bending and/or shortening of the elongate body when positioned in the coronary sinus so as to reduce the curvature of the coronary sinus and thereby reduce the circumference of the mitral valve annulus.

Thus, the present invention takes advantage of the position of the coronary sinus being close to the mitral annulus. This makes repair possible by the use of current catheter-guided techniques.

The coronary veins drain blood from the myocardium to the right atrium. The smaller veins drain blood directly into the atrial cavity, and the larger veins accompany the major arteries and run into the coronary sinus which substantially encircles the mitral orifice and annulus. It runs in the posterior atrioventricular groove, lying in the fatty tissue between the left atrial wall and the ventricular myocardium, before draining into the right atrium between the atrial septum and the post-Eustachian sinus.

In an adult, the course of the coronary sinus may approach within 5-15 mm of the medial attachment of the posterior leaflet of the mitral valve. Preliminary measurements performed at autopsies of adults of normal weight show similar results, with a distance of 5,3±0,6 mm at the medial attachment and about 10 mm at the lateral aspect of the posterior leaflet. The circumference of the coronary sinus was 18,3±2,9 mm at its ostium (giving a diameter of the posterior leaflet of 5,8±0,9 mm) and 9,7±0,6 mm along the lateral aspect of the posterior leaflet (corresponding to a diameter of 3,1±0,2 mm).

The invention will be better understood by the following description of preferred embodiments referring to the appended drawings, in which

Fig. 1 is a cross-sectional view of a part of a heart,

Figs 2 and 3 are schematic views of a first embodiment of a device according to the present invention,

Figs 4-6 are schematic views illustrating an instrument, which may be used when positioning the device shown in Figs 2 and 3 in the coronary sinus,

Fig. 7 is a partial, enlarged view of the first embodiment shown in Fig. 2.

Figs 8 and 9 are schematic views illustrating the positioning of the device of Figs 2 and 3 in the coronary sinus,

Figs 10 and 11 are schematic views illustrating the positioning of a second embodiment of the device according to the present invention in the coronary sinus, and

Figs 12 and 13 are schematic views illustrating the positioning of a third embodiment of the device according to the present invention in the coronary sinus.

Fig 1 is a cross-sectional view through the heart area of the posterior atrioventricular groove 1, which is filled with fatty tissue. It shows the posterior leaflet 2 of the mitral valve and the adjoining parts 3, 4 of the atrial myocardium and the ventricular myocardium. The coronary sinus 5 is shown close to the mitral annulus 6 and behind the attachment 7 of the posterior leaflet 2. Since the coronary sinus 5 substantially encircles the mitral annulus 6, a reduction of the radius of curvature of the bent coronary sinus 5 also will result in a diameter and circumference reduction of the mitral annulus 6.

The device of Fig. 2 comprises an elongate body 8 made of memory metal, e.g. Nitinol, or other similar material which has a memory of an original shape, illustrated in Fig. 3, and can be temporary forced into another shape, illustrated in Fig. 2. This elongate body 8 comprises one, two or more memory metal strings 9 of helical or other shape so as to fit together and be able

of permitting the movements described below. Along the elongate body 8 several hooks 10 are fastened so as to extend radially out therefrom. These hooks 10 are covered by a cover sheet 11 in Fig. 2.

The elongate body 8 is forced into a stretched or extended state by means of a stabilising instrument 12 shown in Fig. 4. This instrument 12 has two arms 13 at a distal end 14 of a rod 15 and a locking means 16 at a proximal end of the rod 15. The distance between the ends of the rod 15 corresponds to the desired length of the elongate body 8 when being inserted into the coronary sinus 5.

The arms 13 are free to move between the position shown in Fig. 4 and a position in alignment with the rod 15, as shown in Fig. 6. The locking means 16 has two locking knobs 17, which are pressed radially outwards from the rod 15 by two spring blades 18. Thus, the elongated body 8 can be pushed over the rod 15 of the stabilising instrument 12, then stretched between the arms 13 and the knobs 17, and finally locked in its stretched state on the stabilising instrument 12 between the arms 13 and the knobs 17, as illustrated in Fig. 5.

The rod 15 may be a metal wire which is relatively stiff between the distal end 14 and the locking means 16 but still so bendable that it will follow the shape of the coronary sinus 5. Proximally of the locking means 16 the metal wire of the stabilising instrument 11 is more pliable to be able to easily follow the bends of the veins.

The above-described elongate body 8 is positioned in the coronary sinus 5 in the following way:

An introduction sheet (not shown) of synthetic material may be used to get access to the venous system. Having reached access to the venous system, a long guiding wire (not shown) of metal is advanced through the introduction sheet and via the venous system to the coronary sinus 5. This guiding wire is provided with X-

ray distance markers so that the position of the guiding wire in the coronary sinus 5 may be monitored.

The elongate body 8 is locked onto the stabilising instrument 12, as shown in Fig. 5, and introduced into the long cover sheet 11 of synthetic material. This aggregate is then pushed through the introduction sheet and the venous system to the coronary sinus 5 riding on the guiding wire. After exact positioning of the elongate body 8 in the coronary sinus 5, as illustrated in Fig. 8 where the mitral valve 19 is shown having a central gap 20, the cover sheet 11 is retracted exposing the elongate body 8 within the coronary sinus 5. This manoeuvre allows the hooks 10 on the elongate body 8 to dig into the walls of the coronary sinus 5 and into the heart. The elongate body 8 is still locked on to the stabilising instrument 12 such that the hooks 10 engage the walls of the coronary sinus 5 in the stretched or extended state of the elongate body 8.

A catheter 21, shown in Fig. 6, is pushed forward on the guiding wire and the rod 15 for releasing the elongate body 8 from the locking means 16 by pressing the spring blades 18 towards the rod 15. This movement releases the knobs 17 as well as the arms 13 from engagement with the elongate body 8 which contracts as illustrated in Fig. 9 and as a result bends towards the mitral valve annulus 6 moving the posterior part thereof forward (shown by arrows in Fig. 9). This movement reduces the circumference of the mitral valve annulus 6 and thereby closes the central gap 20.

Fig. 7 illustrates a part of an arrangement of the wires 9 and the hooks 10 along a peripheral part of the elongate body 8, whereby the elongate body 8 will be asymmetrically contracted resulting in a bending thereof when interconnecting parts 22 of at least some of the hooks 10 are shortened to an original shape.

Figs 10 and 11 illustrate an alternative embodiment of an elongate body 8', which is a solid wire in the

shape of an open U-shaped ring that will engage the wall of the coronary sinus 5 most adjacent to the mitral valve annulus 6 when inserted into the coronary sinus 5. The elongate body 8' consists of a memory metal material which when reverting to its original shape will bend as illustrated in Fig. 11. The return of the open ring 8' to its original shape may be initiated in several ways, as is obvious to the man skilled in the art.

The third embodiment of the elongate body 8", illustrated in Figs 12 and 13, comprises three stent sections 23-25 positioned at one end of the elongate body 8", at the middle thereof and at the other end of the elongate body 8", respectively. These stent sections 23-25 may be positioned in the coronary sinus 5 as illustrated by conventional means, such that their positions are fixed. They are connected by wires 26, 27, which may be manoeuvred from outside the vein system such that the distances between the adjacent stent sections 23, 24 and 24, 25 are reduced. More specifically, these distances are reduced asymmetrically, i.e. more on the side of coronary sinus 5 most adjacent to the posterior part of the mitral valve annulus 6. Thereby, the elongate body 8" is bent, as illustrated in Fig. 13, and presses the coronary sinus 5 against the mitral valve annulus 6 closing the gap 20.

Concludingly, the present invention provides a device placed in the coronary sinus, designed to reduce the dilatation of the mitral annulus. This device is at a distance from the attachment of the posterior leaflet that does not much exceed the distance at which present annuloplasty rings are placed by open surgery techniques, and the coronary sinus is along its entire course large enough to hold such a device. The device could be positioned by catheter technique or any other adequate technique and offers a safer alternative to the current open surgery methods. The device could be designed or heparincoated so as to avoid thrombosis in the coronary

sinus, thus reducing the need for aspirin, ticlopedine or anticoagulant therapy.

It is to be understood that modifications of the above-described device and method can be made by people skilled in the art without departing from the spirit and scope of the invention.

CLAIMS

1. A device for treatment of mitral annulus dilatation, comprising an elongate body (8; 8'; 8") having such dimensions as to be insertable into the coronary sinus (5) and having two states, in a first of which the elongate body (8; 8'; 8") has a shape that is adaptable to the shape of the coronary sinus (5), and to the second of which the elongate body (8; 8'; 8") is transferable from the said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus (5) is reduced as well as the circumference of the mitral valve annulus (6), when the elongate body (8; 8'; 8") is positioned in the coronary sinus (5).

2. A device according to claim 1, further comprising means (9; 22; 26, 27) for the transfer of the elongate body (8; 8") to the second state by bending and shortening it from a larger radius of curvature to a smaller radius of curvature.

3. A device according to claim 2, wherein said transfer means (9; 22; 26, 27) comprises means for bending and shortening the elongate body (8) by a contraction thereof.

4. A device according to claim 1, wherein the elongate body (8; 8') comprises a memory material providing the transfer to the second state.

5. A device according to claim 1 or 2, wherein the elongate body (8) comprises a stent.

6. A device according to claim 2, wherein the elongate body (8") comprises several stent sections (23-25) and said bending means (9; 22; 26, 27) comprises wires (26, 27) for shortening the distance between the stent sections.

7. A method of reducing the circumference of the mitral valve annulus, comprising inserting an elongate body (8; 8'; 8") into the coronary sinus (5) in the vicinity of the posterior leaflet (2) of the mitral

valve, and providing a bending and shortening of the elongate body (8; 8'; 8") when positioned in the coronary sinus (5) so as to reduce the curvature of the coronary sinus (5) and thereby reduce the circumference of the mitral valve annulus (6).

8. A method according to claim 7, wherein said bending and shortening of the elongate body (8; 8") is provided by a contraction thereof.

9. A method according to claim 7 or 8, wherein a memory material is used in the elongate body (8') for providing the transfer to the second state.

10. A method according to claim 7 or 8, wherein the elongate body (8") is made from several stent sections (23-25) and wires (26, 27) are used for shortening the distance between the stent sections (23-25) in order to bend the elongate body (8").

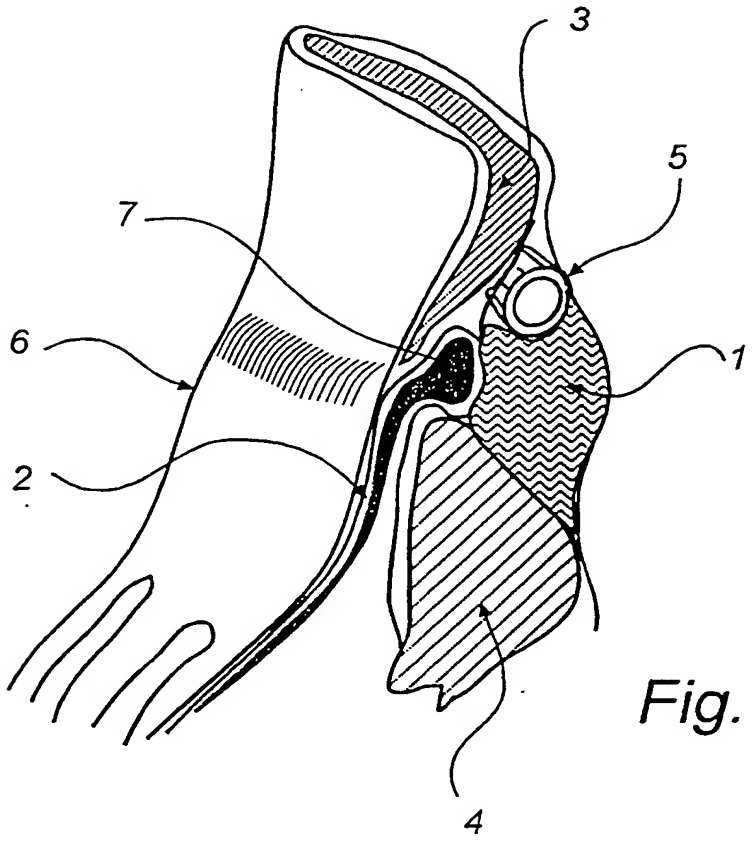


Fig. 1

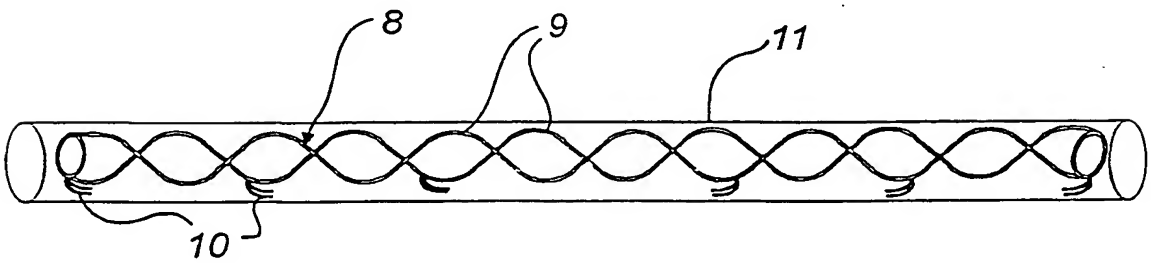


Fig. 2

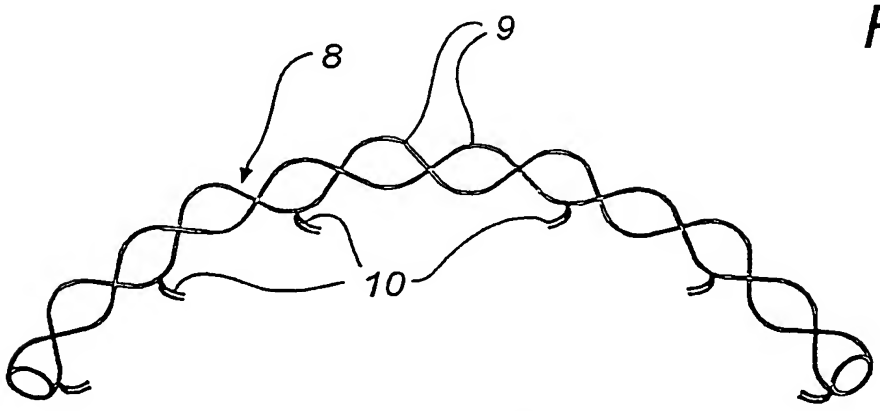


Fig. 3

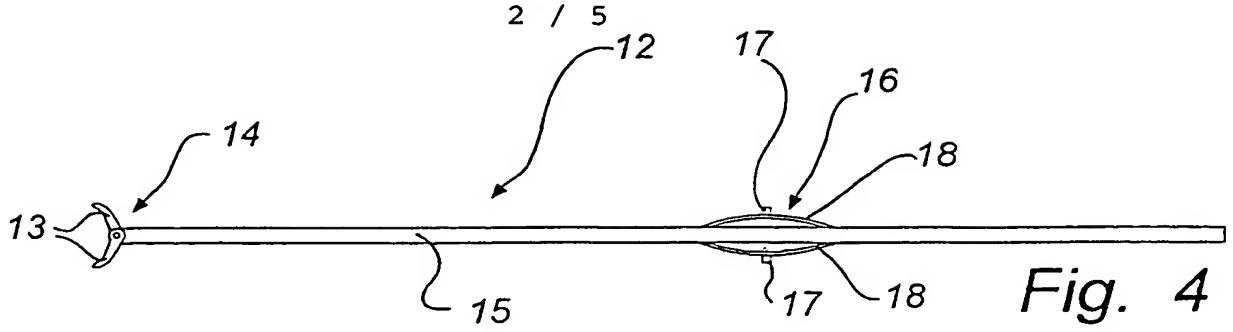


Fig. 4

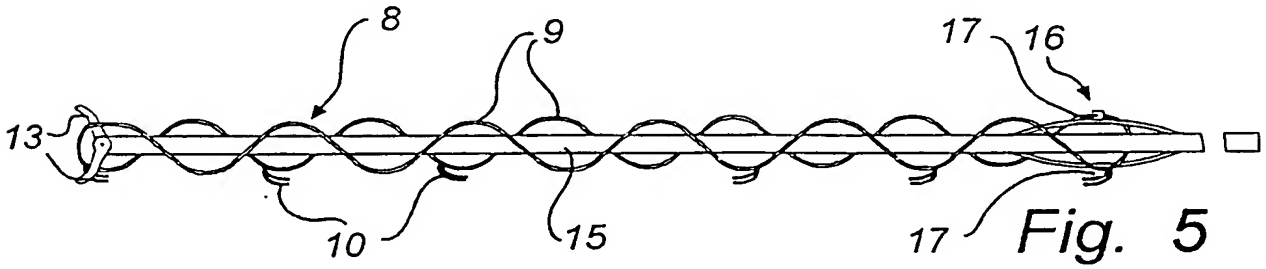


Fig. 5

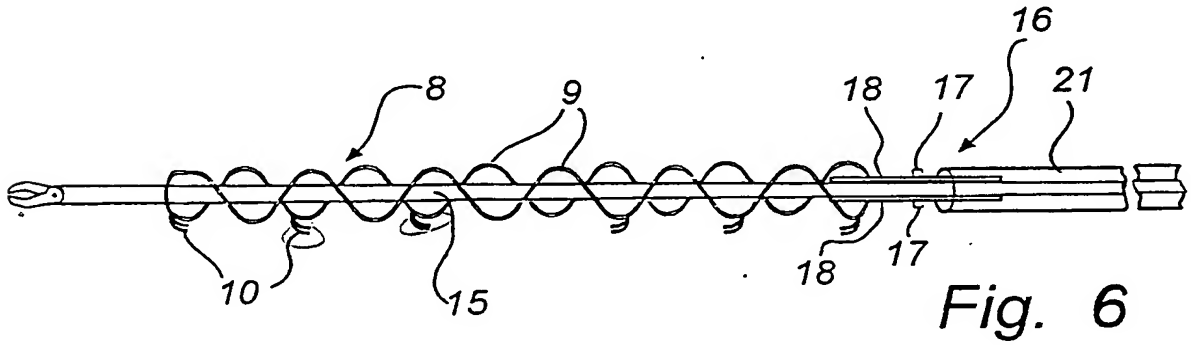


Fig. 6

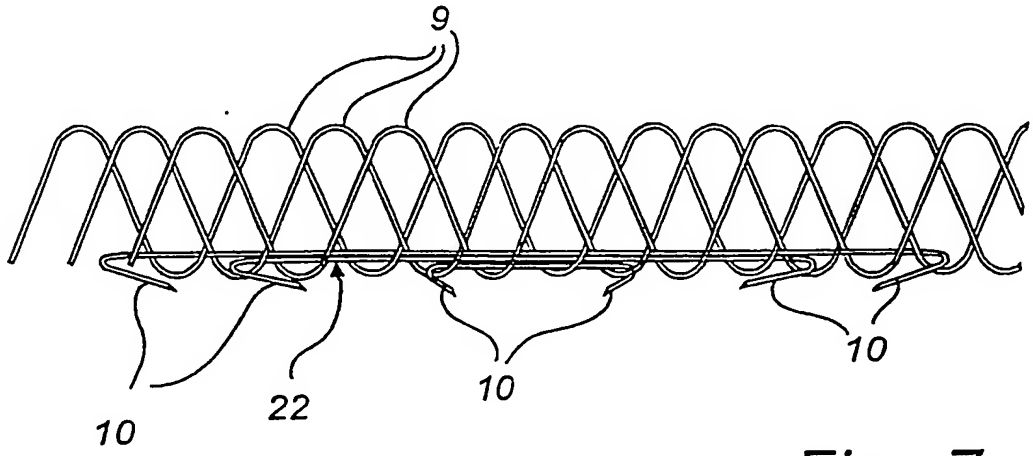


Fig. 7

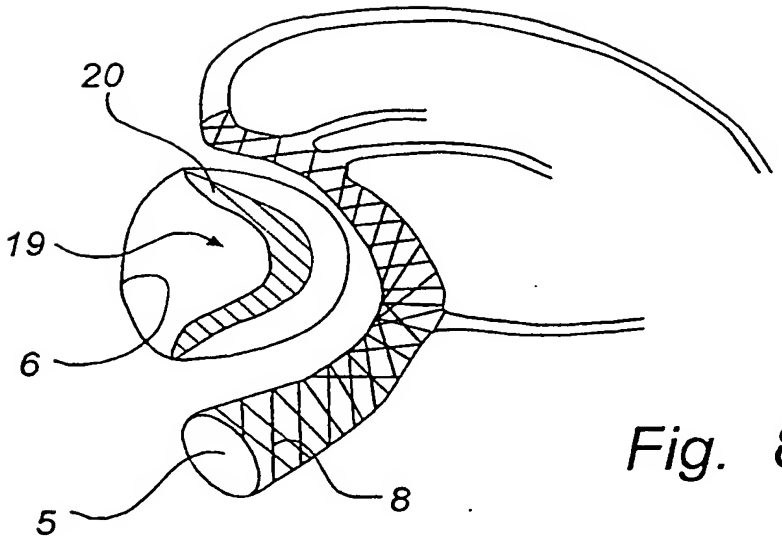


Fig. 8

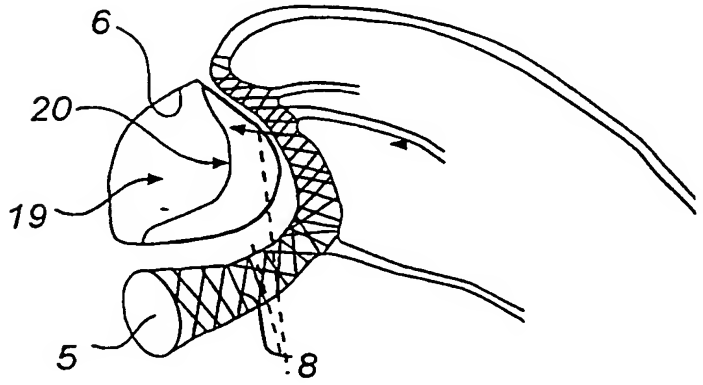


Fig. 9

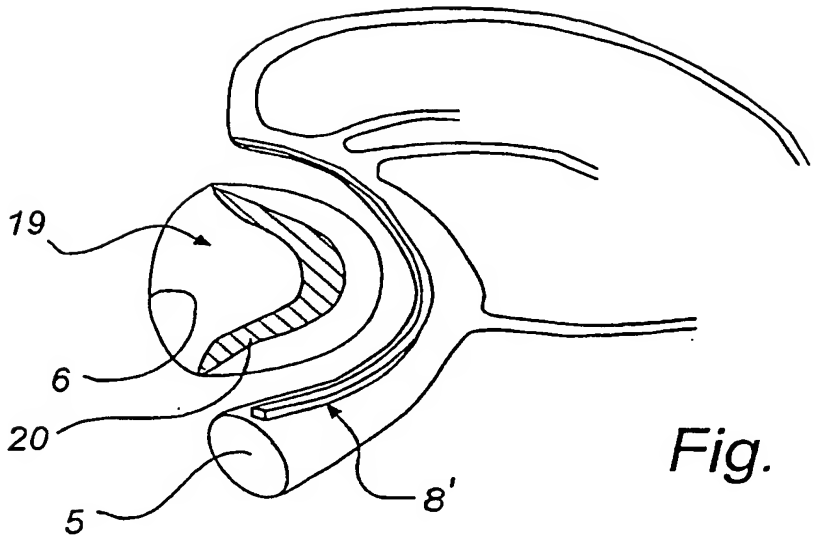


Fig. 10

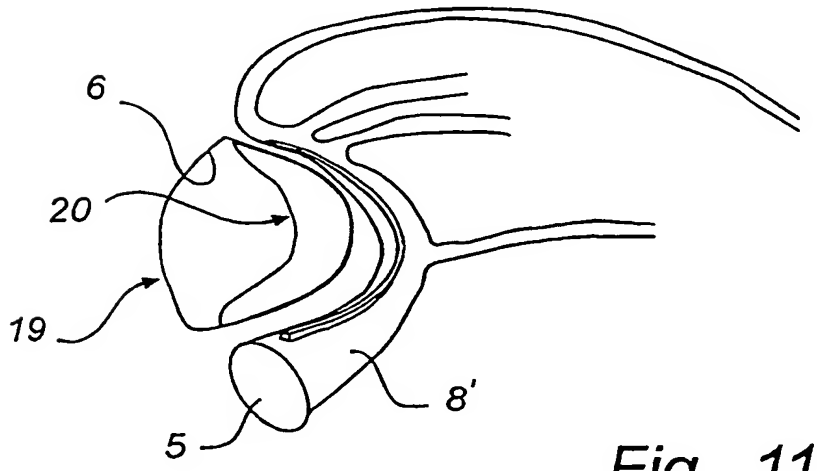


Fig. 11

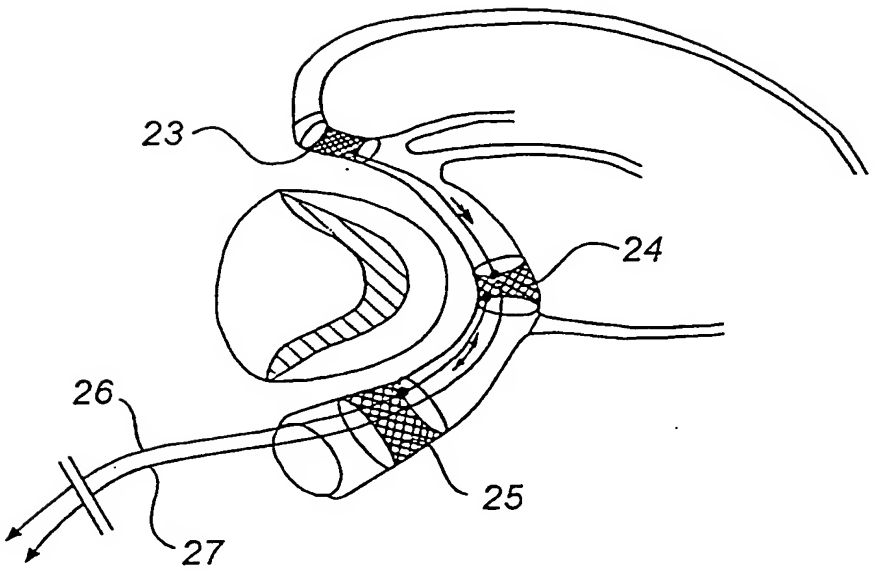


Fig. 12

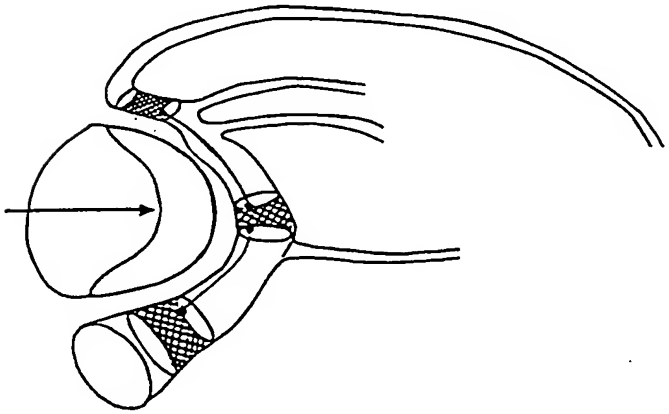


Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01369

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 2/06
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 19605042 A1 (FIGULLA, HANS-REINER), 15 January 1998 (15.01.98), abstract + figure -AC --	1-10
A	EP 0727239 A2 (DAIG CORPORATION), 21 August 1996 (21.08.96), abstract -AB --	1-10
A	US 5163955 A (CHARLES S. LOVE ET AL), 17 November 1992 (17.11.92), abstract -AA -- --------	1-10

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion f the internati nal search	Date f mailing of the international search report
8 Sept 2000	25 -10- 2000
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Hélène Erikson/Els Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

08/05/00

International application No.
PCT/SE 00/01369

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19605042 A1	15/01/98	NONE	
EP 0727239 A2	21/08/96	CA 2150784 A	15/08/96
		CA 2153178 A	15/08/96
		EP 0727238 A	21/08/96
		JP 8266550 A	15/10/96
		JP 9047513 A	18/02/97
		US 5640955 A	24/06/97
		US 5814029 A	29/09/98
		US 5868733 A	09/02/99
US 5163955 A	17/11/92	CA 2101266 A	25/07/92
		EP 0569450 A	18/11/93
		JP 7504091 T	11/05/95
		RO 109501 A	30/03/95
		US 5326370 A	05/07/94
		US 5326371 A	05/07/94
		US 5423887 A	13/06/95
		US 5489298 A	06/02/96
		US 5531784 A	02/07/96
		US 5571174 A	05/11/96
		US 5584878 A	17/12/96
		US 5653749 A	05/08/97
		US 5662705 A	02/09/97
		US 5755782 A	26/05/98
		WO 9212690 A	06/08/92

REC'D 16 JUL 2001
WIPO PCT

TENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC-2004309	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE00/01369	International filing date *(day/month/year)* 28.06.2000	Priority date *(day/month/year)* 29.06.1999
International Patent Classification (IPC) or national classification and IPC A61F 2/06		
Applicant SOLEM, Jan Otto		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 17.01.2001	Date of completion of this report 19.06.2001
Name and mailing address of the IPEA/SE [illegible] Telex: 17978 PATOREG-S Facsimile No. 08-667 72 88	Authorized officer Hélène Erikson / MRo Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE00/01369

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/SE00/01369

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 7-10

because:

☒ the said international application, or the said claims Nos. 7-10
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See PCT Rule 67.1(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The claimed invention relates to a device for treatment of mitral annulus dilation. It comprises an elongate body having two states. In the first state the elongate body is insertable into the coronary sinus. When in position it can be transferred to the second state, where it has a reduced radius of curvature. This results in a reduced radius of curvature of the coronary sinus as well as a reduced circumference of the mitral annulus.

The most relevant documents cited in the search report are the following:
D1 DE 19 605 042
D2 EP 0 727 239 A2
D3 US 5163955

D1 relates to a vessel implant for bridging vascular weaknesses. It has semicircular shell-like body with hooks on it for anchoring in position and tubes attached for pelvic arteries.

D2 refers to a method for ablation and mapping of accessory pathways around mitral valve of left ventricle of the heart. It includes guiding introducers of specific shapes for use within left ventricle for treatment of accessory pathways around the mitral valve.

D3 discloses a heart valve with tissue alignment and clamping. It has two stents, inner stent having tissue alignment members and these extend out to corresponding holes cut in tissue. A piece of tissue is situated between the two stents and it has several holes registered with the tissue alignment members. When the tissue is aligned it forms valve leaflets of a uniform size.

.../...

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V.

It would not be obvious to a person skilled in the art to apply the features from the cited documents and thus arrive at the invention as revealed in claims 1-6. Therefore, the subject matter of these claims fulfils the requirements of novelty, inventive step and industrial applicability according to PCT Article 33(2,3,4).